K011933

NOV 0 2 2001

510(k) Summary of safety and Effectiveness

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact	Owner/ Operator Provalis Diagnostics Limited Newtech Square Deeside Industrial Park Deeside Flintshire CH5 2NT UK
Contact Person:	Mrs Jan Barrack, Regulatory Affairs Manager
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Email:	JanBarrack@Provalis.com
USA contact person	Thomas M Tsakeris
Company	Devices and Diagnostics Consulting Group Inc.
Address:	16809 Briardale Road, Rockville, MD 20855 USA
Telephone:	301 330 2076
Facsimile:	301 330 2568
Email:	ttsak@erols.com
Date Prepared	13th June 2001

2) Device name	Proprietary name: Common name:	Glycosal™ II HbA_{1c} Test Prescription Home use Test for the Detection of Glycated Hemoglobin in Human Whole Blood.
	Classification:	ASSAY, GLYCOSYLATED HEMOGLOBIN
3) Predicate Device	The Glycosal™ II HbA_{1c} test is substantially equivalent to other products in commercial distribution for similar use, including the Glycosal™ HbA_{1c} test (primary predicate device) and the Metrika DRX HbA_{1c}, for prescription home use test (secondary predicate device).	
4) Device Description	Instrument read, single use *in vitro* test for the quantitative determination of glycated hemoglobin (GHb) in diabetics.	
5) Intended use	The Glycosal™ II HbA_{1c} test is an affinity chromatography method and is intended for the in-vitro quantitative determination of HbA_{1c} in capillary blood taken from a finger prick. The test is indicated for use by diabetics for monitoring the time averaged blood glucose levels of known diabetics as an indicator of overall glycaemic control. The Glycosal™ II HbA_{1c} test is intended for use as a prescription home use test.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 0 2 2001

Provalis Diagnostics Ltd.
c/o Mr. Thomas M. Tsakeris
Devices and Diagnostics Consulting Group
16809n Briardale Road
Rockville, MD 20855

Re: k011933
Trade/Device Name: Glycosal™ II HbA_{1c} Test
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP
Dated: September 19, 2001
Received: September 20, 2001

Dear Mr. Tsakeris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011933

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Intended Use/Indications for Use Statement

510(k) Number: *Unknown-not yet assigned by FDA*

Device Name: Glycosal™ II HbA_{1c} Test

Intended Use/Indications for Use Statement:

The Glycosal™ II HbA_{1c} assay is an affinity chromatography method and is intended for the in-vitro quantitative determination of HbA_{1c} in capillary blood taken from a finger prick.

The test is indicated for monitoring the time averaged blood glucose levels of known diabetics, for use at home by diabetics as an indicator of overall glycaemic control.

The Glycosal™ II HbA_{1c} assay is intended for prescription home use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K011933